UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

DAPHNE MARQUE GANAHL, *Plaintiff,*	)	
vs.	)	1:10-cv-1518-JMS-TAB
STRYKER CORPORATION, STRYKER LEIBINGER USA, STRYKER SALES CORPORATION and CONTRACT MEDICAL MANUFACTURING, LLC, *Defendant.*	)	

ORDER

Plaintiff Daphne Marque Ganahl brings this action against Defendants Stryker Corporation, Stryker Leibinger USA, Stryker Sales Corporation and Contract Medican Manufacturing, LLC ("Defendants"), who sold her a medical device that infected her after it was implanted. Presently before the Court is Defendants' Motion to Dismiss. [Dkt. 10.]

I.

STANDARD OF REVIEW FOR A MOTION TO DISMISS

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009). A claim only has facial plausibility when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged[,]" not when the plaintiff only raises a "sheer possibility that the defendant has acted unlawfully." *Id*. In considering these issues, we accept all well-pleaded facts as true, draw all inferences in favor of the plaintiff, and resolve all ambiguities in favor of the plaintiff. *Canedy v. Boardman*, 16 F.3d 183, 188 (7th Cir.1994).

II.

BACKGROUND

Ms. Ganahl's Complaint asserts the following facts, which are taken as true for purposes of this ruling.

Defendants are corporations that manufacturer and sell medical devices. [Dkt. 1-3 at 1.] Between November 2007 and October 2008, Defendants sold a device to correct defects in the lower/upper jaw, face, or cranium ("Cranial Implant") with approval from the Food and Drug Administration ("FDA"). [*Id.* at ¶ 12.]

At an unspecified time, Defendants sold a Cranial Implant to Ms. Ganahl, whose health-care providers surgically implanted the device into her head. [Dkt. 1-3 at ¶¶ 16-17.] After the surgery, the Cranial Implant infected her, and she had to have it surgically removed. [*Id.* at ¶¶ 19-20.]

Ms. Ganahl later learned that the Defendants failed to submit the Cranial Implant to a sterilization validation in accordance with the standards set forth by the FDA, [*id.* at ¶ 19], and the device was defective when it was sold to her. [*Id.* at ¶ 22.]

In October 2008, the Defendants admitted that they could not assure the sterility of the Cranial Implants, and that implanting them created risk of serious infection. [*Id.* at ¶ 23.] Thus, in December 2008, the FDA issued a Class I Recall for the devices, which required their removal from the market and corrective action taken by Defendants. [*Id.* at ¶ 24.]

As a result of the implantation of the Cranial Implant, Ms. Ganahl suffered, and continues to suffer, "injury and emotional damage, including but not limited to past, present, and future physical and mental pain and suffering, emotional distress, and past, present, and future medical, hospital, monitoring, rehabilitative, and pharmaceutical expenses, and lost income and earning capacity." [*Id.* at ¶ 9.]

In October 2010, Ms. Ganahl filed this action in Marion County Circuit Court, asserting claims of product liability, negligence, breach of contract, and violation of Indiana's Crime Victims Statute, Ind. Code § 34-24-3-1. [*Id.* at ¶¶ 39-71.] Defendants removed the case to this Court pursuant to 28 U.S.C. §§ 1332, 1441, and 1446. [Dkt. 1.]

DISCUSSION

Ms. Ganahl alleges that Defendants are liable for defective manufacture, failure to warn, negligent manufacture, breach of express warranty, breach of implied warranty of merchantability, and violation of Indiana's Crime Victims Statute, Ind. Code § 34-24-3-1. [Dkt. 1-3 ¶¶ 39-71.] Defendants argue that the case should be dismissed because she failed to plead her claim under the Indiana Product Liability Act ("IPLA"). [Dkt. 11 at 3.] They further argue that even if she had, each count of her complaint fails to survive a motion to dismiss.

A) Pleading Under the IPLA

Ms. Ganahl's complaint does not mention the IPLA. [Dkt. 1-3.] Defendants argue that because the IPLA applies to all product liability actions, her failure to plead her claims under the statute warrant dismissal. [Dkt. 11 at 3.]

Although it is common practice for a plaintiff to cite to statutes and legal rules in its complaint, however, nothing in the Federal Rules of Civil Procedure requires a plaintiff to do so. *Bartholet v. Reishauer A.G. (Zurich)*, 953 F.2d 1073, 1078 (7th Cir.1992). A complaint "need not identify a legal theory, and specifying an incorrect theory is not fatal." *Id.* Therefore, her mere failure to specifically cite the IPLA does not render her complaint susceptible to a motion to dismiss.

At this point, however, the Court must clarify the law governing this case. Because this Court is exercising diversity jurisdiction, it will apply the laws of Indiana. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). And both parties argue Indiana law as well. The Indiana

Product Liability Act ("IPLA") governs "all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by the product." Ind. Code § 34-20-1-1. The Indiana Supreme Court has held that it is "clear that the legislature intended that the IPLA govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *American Intern. Ins. Co. v. Gastite*, 2009 WL 1383277, *2 (S.D.Ind.). When a consumer seeks to recover from a manufacturer for physical harm for a product, the IPLA provides for a single cause of action, regardless of the plaintiff's substantive legal theories. *Id*. Therefore, although failure to plead under the IPLA is not grounds for dismissal, the Court will evaluate Ms. Gahnal's claims in light of this statute. *See* Ind. Code § 34-20-1-1, *et seq.*

B) Products Liability Claim

Ms. Ganahl's claim for products liability is in two counts: I) strict liability in tort for defective manufacture, and II) strict liability for failure to warn. [Dkt. 1-3 at 9-10.]

Defendants argue that the IPLA does not recognize a strict liability standard in the context of a failure to warn claim. [Dkt. 11 at 3.] In response, Ms. Ganahl maintains that failure to warn reflects a product defect, and that the statute calls for strict liability with respect to product defects. [Dkt. 14 at 6-7.]

As a general rule, a manufacturer is strictly liable for a defective product. *Id*. § 34-20-2-2. If the plaintiff alleges that the product was defectively designed, or that the manufacturer failed to provide adequate warnings or instructions regarding the use of the product, however, then the plaintiff must establish that the manufacturer failed to exercise reasonable care under the circumstances. *Id*. *See also American Intern. Ins. Co.*, 2009 WL 1383277 at *4; *see also* I. C. 34-20-2-2. However, the IPLA also says that "a product is defective . . . if the seller fails to . . . give reasonable warnings of danger about the product." Ind. Code § 34-20-2-2.

Because § 34-20-2-2 unequivocally applies a negligence standard to independent failure to warn claims but recognizes that failure to warn can constitute a product defect, Ms. Ganahl's "strict liability failure to warn" claim is only proper insofar as it actually supports a more comprehensive claim for defective manufacture. In any event, "[i]t is improper for Plaintiff to maintain [two] separate counts for the same tort, i.e. product liability." *American Intern. Ins. Co.*, 2009 WL 1383277 at *4.

The Court therefore finds it appropriate to merge Count I and Count II together into one statutory claim under the IPLA. However, Ms. Ganahl may support her IPLA claim with appropriate and separate legal theories as contemplated by the IPLA. *See Bourne v. Gilman, Inc*., 2005 WL 1703201, at *3 n. 2 (S.D.Ind.).

C) State-Law Negligence Claims

In Count III of her complaint, Ms. Ganahl asserts a state-law claim for negligent manufacture. As the Court previously mentioned, the IPLA provides the sole cause of action for a manufacturing defect in a product liability case. *American Intern. Ins. Co*, 2009 WL 1383277 at *2. To the extent that Ms. Ganahl pleads a state-law negligence claim against Defendants in addition to her IPLA claim, it is dismissed. *Ryan ex rel. Estate of Ryan v. Philip Morris USA*, Inc. 2006 WL 449207 (N.D.Ind.). This dismissal does not, however, prevent her from making negligence arguments in accordance with her single statutory claim under the IPLA. *See Bourne v. Gilman, Inc*., 2005 WL 1703201 at *3.

D) Warranty Claims

Ms. Ganahl also pleads two warranty claims: breach of express warranty in Count IV and breach of implied warranty of merchantability in Count V.

The parties agree that both of Ms. Ganahl's warranty claims required that Defendants be put on notice of the alleged defect prior to this action. *See* I.C. § 26-1-2-607(3)(a). Defendants

argue that Ms. Ganahl failed to allege such notice, and, accordingly, both of her warranty claims fail. [Dkt. 11 at 4.] Ms. Ganahl contends, however, that the recall of the device itself put Defendants on proper notice of the alleged defect, so that her complaint complies with § 26-1-2-607(3)(a). [Dkt. 14 at 9-10.]

The law is clear that "[a] complaint fails to state a cause of action if it lacks an allegation that a necessary condition precedent has been performed." Fed. Rule of Civ. Pro. 9(c); *The Cincinnati Ins. Companies v. Hamilton Beach*, 2006 U.S. Dist. LEXIS 9807 at 11 (N.D. Ind.). A plaintiff must plead having given such notice to comply with Rule 9(c). Even though "it suffices [under Rule 9] to allege generally that all conditions precedent have occurred or been performed," Ms. Ganahl's complaint does not allege that she provided Defendant notice of any kind—specific or general—or that she performed any conditions precedent. [Dkt. 1-3 at ¶¶ 59-62.] For that reason, her warranty claims do not comply with Rule 9(c). The Court therefore dismisses Counts IV and V.

The Court notes that Defendants have argued other defects with Ms. Ganahl's warranty claims, however, because the notice issue is dispositive the Court does not reach them.

E) Claims under Ind. Code § 34-24-3-3

In Count VI, Ms. Ganahl alleges that Defendants acted in violation of Ind. Code § 35-43-5-3, criminal provisions addressing the dissemination of false and misleading information. [Dkt. 1-3 at 15.] Defendants argue that her claims are not pled with the specificity warranted by the statute.

Specifically, Ms. Ganahl pleads:

> The Sellers disseminated advertising to the public prior to the sale of the Implanted Device to the health care providers and [Ms. Ganahl]. The Sellers knew the advertising contained misleading and/or deceptive information. The Sellers failed to reveal to the health care providers and [Ms. Ganahl] material facts in light of the representations that it made. The advertisements were disseminated to

> the health care providers and [Ms. Ganahl] with the intent to promote the sale of the Implanted Device. The dissemination . . . was a violation of Indiana Code § 35-43-5-3(a)(9).

[Dkt. 1-3 at 15.] She does not, however, identify anything about the nature of the advertisement, any potentially false or misleading information contained therein, or even that she read such an advertisement before purchasing the Cranial Implant.

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. Rule of Civ. Pro. 9(b). Even if Ms. Ganahl is not alleging fraud *per se*, the Supreme Court recently made clear, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to overcome a motion to dismiss. *Iqbal*, 129 S.Ct. at 1948; Fed. Rule Civ. Pro. 8(a). Accordingly, Ms. Ganahl's conclusory statements are not sufficient to state a claim for a violation of § 35-43-5-3(a)(9). *See Wayne House v. First American Title Co.*, 883 N.E.2d 197, 203 (Ind. Ct. App. 2008) (failure to allege facts to establish violation of § 35-43-5-3(a)(9) causes claim to fail on a motion to dismiss.").

Also in Count VI, Ms. Ganahl alleges that Defendants:

> knowingly and intentionally made false and/or misleading written statements relating to the Implanted Device with the intent to obtain the property of [Ms. Ganahl]. The written statements were made in violation of I.C. § 35-43-5-3(a)(2).

[Dkt. 11 at 6.] Similar to her § 35-43-5-3(a)(9) claim, however, Ms. Ganahl fails to provide any detail regarding this accusation.

To maintain an action under § 35-43-5-3(a)(2), a plaintiff must present "proof of a false or misleading written statement." *Ecker v. Rochester Ford New Holland*, 694 N.E.2d 289, 291 (Ind. Ct. App. 1998). Because Ms. Ganahl's claim fails to identify the alleged written statement Defendants allegedly made, her vague claims that they intentionally disseminated such false

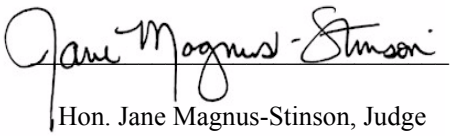
and/or misleading written statements must fail. *See Iqbal*, 129 S.Ct. at 1948; *see also Wayne House*, 883 N.E.2d at 203.

Ms. Ganahl's Count VI claims that Defendants violated § 35-43-5-3(a)(9) and § 35-43-5-3(a)(2) are therefore both dismissed.

CONCLUSION

For the foregoing reasons, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Dismiss. [Dkt. 10.] The Court further merges Counts I and II into a single statutory claim for product liability under the IPLA but denies the motion to the extent it asserts Ms. Ganahl has failed to state a claim under the IPLA. As to Counts III,[1] IV, V, and VI Defendants' motion is granted. Assuming a sufficient factual foundation exists to do so, Ms. Ganahl shall have fourteen (14) days to file an amended complaint addressing the deficiencies in these stricken claims.

02/15/2011



Hon. Jane Magnus-Stinson, Judge
United States District Court
Southern District of Indiana

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[1] Again, the dismissal of Ms. Ganahl's negligence is claim is without prejudice to the proper assertion of a negligence theory under the IPLA.

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